

REMARKS

Claims 1-28 have been canceled. Claims 29-31 have been withdrawn. New claims 32-34 have been added to recite combinations of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine (LAF237) in free form or in an acid addition salt form and at least one peroxisome proliferators-activated receptor α (PPAR α) compound in free form or in an acid addition salt form. Applicant submits that new claims 32-34 are consistent in scope with the originally elected invention as seen in claims 21-28. In addition, new claims 32-34 do not introduce new matter.

Claims 29-31 are withdrawn, they have been amended to have the same limitations as new claims 32-34 such that later these withdrawn claims may be rejoined when the elected claims are in conditions for allowance.

As claims 1-28 have been canceled, the rejections are moot with respect to these claims. In the following sections, Applicant respectfully traverses the rejections as it applies to new claims 32-34.

Rejection for obvious-type double patenting:

The examiner has rejected the claims for obviousness-type of double patenting over claims 1-10 of U.S. Application No. 11/571,994 (the '994 application) on the grounds that the claims of the present inventions are not patentably distinct over claims 1-10 of the '994 application because the '994 application claims are drawn to a composition comprising a PPAR α agonist in combination with GLP-1 agonist and DPP-IV inhibitors are GLP-1 analogues (citing page 6, para. 77, lines 1-5). Applicant respectfully disagrees for the following reasons.

Applicant submits that DPP-IV inhibitors are not GLP-1 analogues. DPP-IV binds to, cleaves and inactivates proteins/peptides such as GLP-1. GLP-1 is well known to stimulate insulin releasing by binding to GLP-1 receptor. In addition, the '994 application recites in para. 77 that DPP-IV can be used as an inhibitor of an enzyme that inactivates GLP-1. In contrast, GLP-1 analogues are derived from GLP-1 peptide and mimic actions of the naturally occurring GLP-1. See Green et al., *J. Pharmacology & Experimental Therapeutics*, 318(2): 914-921 (2006), in which the authors state that to overcome the degradation of GLP-1 by DPP-IV, there have been developments on DPP-IV inhibitors and DPP-IV resistant GLP-1 analogues. See *Id.* the paragraph bridging pages 914 and 915. In addition, Chirico et al., *Review of Endocrinology*, 42-46 (2007), further distinguish GLP-1 analogues from DPP-IV inhibitors on function aspects.

Accordingly, the combination of a PPAR α agonist and GLP-1 agonist recited in the '994 application claims 1-10 are substantially distinct from the combination recited in the present invention, and Applicant respectfully request that the examiner withdraw the rejection.

Rejection under 35 U.S.C. §102(e):

The examiner has rejected claims 21-26 under 35 U.S.C. §102(e) on the grounds that Caplan et al. anticipates these claims. Applicant note that claims 21-26 have been canceled and the rejection is moot with respect to these claims. With respect to new claims 32-34, Applicant submits that Caplan et al. fail to teach use of LAF237 in combination with DPP-IV inhibitors, thus Caplan et al. fail to anticipate the invention recited in new claims 32-34. Applicant respectfully asks that the reject be withdrawn.

Rejection under 35 U.S.C. §103(a):

The examiner has rejected claims 27 and 28 under 35 U.S.C §103(a) for being obvious over Caplan et al. in view of Villhauer. Applicant notes that claims 27 and 28 have been canceled and the rejection is moot with respect to these claims. With respect to new claims 32-34, Applicant submits that the prior art references combined together fail to teach/disclose all the elements claimed in new claims 32-34. The examiner concedes that Caplan et al. fails to teach use of LAF237 in combination with DPP-IV inhibitors, and Villhauer fails to remedy the deficiency in Caplan et al. Applicant notes that teaching-all-elements of the invention by the prior art references is still a crucial requirement in the newly issued examination guideline regarding obviousness after KSR (See Federal Register, Vol 72 (195)).

Furthermore, Applicant submits that the disclosure of the present invention shows that combination of LAF237 with a PPAR α compound micronized fenofibrate results in surprisingly synergistic therapeutic effects (unexpected results). See page 18, the last paragraph through page 19, 5th paragraph. Applicant notes that the newly issued examination guideline allows unexpected results (such as synergistic therapeutic effects as shown herein) as evidence for arguing non-obviousness of the invention.

Based on the above, Applicant respectfully request that the rejection be withdrawn.


Applicant believes this reply is fully responsive to all the outstanding issues. In view of the above, an early Notice of Allowance is respectfully requested. Please apply any charges not covered, or any credits, to Deposit Account 19-0134.

Respectfully submitted,

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Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-9276


Cynthia H. Zhang
Attorney for Applicant
Reg. No. 53,827

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